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Government Resolution on GMO Registration for Environmental Release

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Report Highlights:

On September 23rd, 2013, the Government of the Russian Federation adopted the Resolution (No. 839) "On the State Registration of Genetically-Engineered-Modified Organisms Intended for Release into the Environment as well as Products Derived from the Use of Such Organisms or Containing Such Organisms". The Resolution approved the rules of registration of genetically engineered organisms and products and these rules come into force on July 1st, 2014. By this date the authorized ministries and federal services must update or develop procedures for the beginning of registration. The Resolution will not have any immediate effect on the cultivation of biotech crops in Russia, but creates an approval process to make such cultivation possible.

General Information:

On September 25th, 2013, the Government of Russia published a Resolution on the state registration of genetically modified organisms for release into environment. This Government Resolution - No. 839 of September 23, 2013 “On the State Registration of Genetically-Engineered-Modified Organisms Intended for Release into the Environment as well as Products Derived from the Use of such Organisms or Containing Such Organisms” - can be found at <http://government.ru/docs/6128>. The Resolution approves the rules and procedures (the Rules) for registration of “genetically-engineered-modified organisms” (hereinafter – GMOs) for different purposes, including their release into the environment. The creation of an approval procedure for release of GMOs into the environment is a necessary step for any possible cultivation of GMO plants in Russia. The Rules define functions of different government agencies in registration and oversight of GMOs:

- The Ministry of Health of the Russian Federation will register modified organisms used for production of human pharmaceuticals;
- The Federal Service for Surveillance in the Sphere of Public Health (at the Ministry of Health of the Russian Federation) will register modified organisms used for manufacturing of medical devices;
- The Federal Service for Surveillance of Consumer Rights Protection and Human Welfare will register modified organisms used for the production of raw materials for food production and food products;
- The Federal Service for Veterinary and Phytosanitary Surveillance will register modified plants and animals intended for breeding and growing on the territory of the Russian Federation; modified microorganisms of agricultural use; modified organisms used to production of feeds and feed additives for animals; modified organisms used for the production of veterinary drugs, as well as feeds and feed additives for animals and veterinary drugs obtained with use of modified organisms or containing such organisms.

The Rules authorize the Ministry of Health of the Russian Federation to conduct and monitor the Consolidated Register of all genetically modified organisms and products. The Rules also determine general requirements for documents submitted by applicants for registration of genetically modified organisms and products. For registration of organisms and products for release into the environment one of the key steps will be receiving a positive assessment of ecological impact to be conducted by the Federal Service for Surveillance in the Sphere of Environmental Management.

Most of the Rules will come to force on July 1, 2014. Prior to this date Ministries and Federal Services will develop appropriate documents for implementation of these Rules.

The unofficial translation of Government Resolution No. 839 of September 23, 2013, and the Rules approved by this Resolution are in Attachments 1 and 2.

Background

Prior to this Government Resolution being adopted, Russia did not have a mechanism for release of genetically modified plants into the environment. This resulted in a de-facto ban on cultivation of any genetically engineered plants in Russia. In October 2010, Russia adopted a Federal Law that allowed the Government itself to develop a registration procedure for the cultivation of biotech crops through

issuing of a Resolution of the Government. By June 2011 the Ministry of Economic Development prepared a draft government resolution on the state registration of genetically modified organisms for release into the environment (for more information on the process of adoption of the Government resolution on registration of genetically modified organisms and products into the environment see FAS/Moscow GAIN Reports, including [Agricultural Biotechnology Annual 2013](#)). After discussions and changes, on September 23rd, 2013, the Resolution was adopted.

Attachment 1. Government Resolution No. 839 of September 23, 2013

RESOLUTION of the Government of the Russian Federation ON THE STATE REGISTRATION OF GENETICALLY-ENGINEERED-MODIFIED ORGANISMS INTENDED FOR RELEASE INTO THE ENVIRONMENT AS WELL AS PRODUCTS DERIVED FROM THE USE OF SUCH ORGANISMS OR CONTAINING SUCH ORGANISMS

In accordance with Article 7 of the Federal Law "On the State Regulation in the Field of Gene Engineering Activity" the Government of the Russian Federation decides the following:

1. Approve the attached Rules of state registration of genetically-engineered-modified organisms intended for release into the environment, as well as of products derived from the use of such organisms, or containing such organisms;
2. The Ministry of Agriculture of the Russian Federation and the Federal Service for Surveillance of Consumer Rights Protection and Human Welfare to ensure the transfer to the Ministry of Health of the Russian Federation of the available information on genetically-engineered-modified organisms and products derived from the use of such organisms registered before the entry into force of this Resolution for inclusion in the consolidated state Register of genetically-engineered-modified organisms, as well as products derived from the use of such organisms, or containing such organisms;
3. The Ministry of Education and Science of the Russian Federation to approve:
 - a) before January 1, 2014, the All-Russian Classifier of transformational events;
 - b) before May 1, 2014, in coordination with the Ministry of Health of the Russian Federation, the Ministry of Agriculture of the Russian Federation and the Federal Service for Surveillance of Consumer Rights Protection and Human Welfare:
 - the form of the certificate of the state registration of genetically-engineered-modified organisms intended for release into the environment;
 - the form of the certificate of the state registration of products derived from such organisms, or containing such organisms;
4. To establish that the Certificates of state registration of genetically-engineered-modified organism or certificates of state registration of products derived from genetically-engineered-modified organism issued before the entry into force of the Rules approved by this Resolution stay valid until the expiration of the indicated period;
5. To establish that in order to ensure the necessary level of safe use of the results of genetic-engineering activity the Ministry of Health of the Russian Federation, the Federal Service for Surveillance of Consumer Rights Protection and Human Welfare, the Federal Service for

Surveillance of Human Health and the Federal Service for Veterinary and Phytosanitary Surveillance conduct monitoring of the impact on humans and the environment of genetically-engineered-modified organisms and products, derived from such organisms, or containing such organisms.

The Federal Service for Surveillance of Consumer Rights Protection and Human Welfare, the Federal Service for Surveillance of Human Health and the Federal Service for Veterinary and Phytosanitary Surveillance forward the information on the results of conducted monitoring to the Ministry of Health of the Russian Federation;

6. The Ministry of Health of the Russian Federation, The Ministry of Agriculture of the Russian Federation and the Federal Service for Surveillance of Consumer Rights Protection and Human Welfare within their established competence to approve before May 1, 2014 the order of conducting the monitoring referred to in paragraph 5 of this Resolution;
7. The Ministry of Health of the Russian Federation in concurrence with the Ministry of Mass Communication of the Russian Federation, Ministry of Education and Science of the Russian Federation, Ministry of Agriculture of the Russian Federation and the Federal Service for Surveillance of Consumer Rights Protection and Human Welfare to approve before January 1, 2014 the procedure of conducting the consolidated state Register of genetically-engineered-modified organisms, as well as products derived from such organisms, or containing such organisms;
8. To establish that the powers provided for in this Resolution are implemented within the limits of maximum number of employees of the relevant federal executive authorities fixed by the Government of the Russian Federation and budget allocations envisaged in the federal budget for administration and management in the field of these functions;
9. To recognized as repealed:
 - Resolution of the Government of the Russian Federation of February 16, 2001, No. 120 "On the state registration of genetically-engineered-modified organisms" (Collected Legislation of the Russian Federation, 2001, No. 9, Art. 860);
 - Resolution of the Government of the Russian Federation of January 18, 2002, No. 26 "On the state registration of feeds derived from genetically-engineered-modified organisms" (Collected Legislation of the Russian Federation, 2002, No. 4, Art. 323);
 - Resolution of the Government of the Russian Federation of July 14, 2006, No. 422 "On Amending Resolution of the Government of the Russian Federation of January 18, 2002, No. 26" (Collected legislation of the Russian Federation, 2006, No. 30, Art. 3389);
10. This Resolution shall enter into force on July 1, 2014, except articles 3, 6, and 7.

Chairman of the Government
of the Russian Federation

Dmitry Medvedev

Attachment 2. Rules of State Registration of Genetically-Engineered-Modified Organisms Intended for Release into the Environment as well as Products Derived from the Use of Such Organisms or Containing Such Organisms

APPROVED

by Resolution of the Government of the Russian Federation
No. 839 of September 23, 2013

RULES

OF STATE REGISTRATION OF GENETICALLY-ENGINEERED-MODIFIED ORGANISMS INTENDED FOR RELEASE INTO THE ENVIRONMENT AS WELL AS PRODUCTS DERIVED FROM THE USE OF SUCH ORGANISMS OR CONTAINING SUCH ORGANISMS

I. General Provisions

1. These Rules shall set the order of the state registration of genetically-engineered-modified organisms intended for release into the environment, as well as products, derived from such organisms, or containing such organisms (hereinafter referred to as - modified organisms, products);

2. Are not subject to the state registration:

- Modified organisms used for conducting expertise and research work in accordance with established sanitary Rules and standards;
- Products obtained by combining, processing or reprocessing of the registered products containing modified organisms, if such processing and reprocessing does not alter the genetic material of the products;

3. State registration is carried out by the following federal executive agencies (hereinafter - the registration authorities):

- The Ministry of Health of the Russian Federation – of modified organisms used for production of human pharmaceuticals for medical use, as well as human pharmaceuticals for medical use obtained with using modified organisms or containing such organisms;
- The Federal Service for Surveillance of Human Health – of modified organisms used for manufacturing of medical devices, as well as medical devices, obtained with use of modified organisms or containing such organisms;
- The Federal Service for Surveillance of Consumer Rights Protection and Human Welfare – of modified organisms used for the production of food raw materials and food products as well as of food raw materials and food products obtained with using modified organisms or containing such organisms;
- The Federal Service for Veterinary and Phytosanitary Surveillance - of the modified plants and animals intended for breeding and growing on the territory of the Russian Federation; of modified microorganisms of agricultural use; of modified organisms used to production of feeds and feed additives for animals; of modified organisms used for the production of veterinary drugs, as well as feeds and feed additives for animals and veterinary drugs obtained with use of modified organisms or containing such organisms;

4. The state registration of products, which are human pharmaceuticals and medical devices, is carried out within the established procedures of its state registration in accordance with the federal law "On Circulation of Human Pharmaceuticals" and "On the Basics of Health Care of the Citizens of the Russian Federation";

5. Information on registered modified organisms and products is included in the consolidated State Register of genetic engineered-modified organisms, and of products, derived from such organisms, or containing such organisms (hereinafter – Consolidated Register);

6. If the legislation of the Customs Union and of the international treaties of the Russian Federation establish another order of state registration of products, this order applies followed by the inclusion of relevant information of products in the Consolidated Register;
7. Certificates of state registration of genetically-engineered-modified organisms intended for release into the environment, and certificates of state registration of products obtained with the use of such organisms, or containing such organisms (hereinafter - certificates of the state registration of modified organisms, certificates of the state registration of products) are issued by the registration authorities and have unlimited validity;
8. In the case of discovery by the registration authority after ongoing monitoring of the effects of genetically-engineered-modified organisms and products obtained with use of such organisms or containing such organisms on humans and the environment, confirmed by conclusions of expertise (studies) provided for in paragraph 11 of these Rules, of the negative impact of modified organism and (or) of products on health of humans, animals, plants, and (or) on the environment the certificate issued by registration authority may be revoked or it may be amended in the part of the establishment of special conditions of use of the modified organism or products;
9. The Ministry of Healthcare of the Russian Federation and other registration authorities carry out inter-institutional information interaction in accordance with the Federal Law "On the Organization of State and Municipal Services".

II. State registration of modified organisms

10. Modified organisms are subject to state registration with consideration of their intended use;
11. There are the following kinds of intended use of modified organisms:
- a) production of human pharmaceuticals for medical use;
 - b) production of medical devices;
 - c) production of food raw materials and food products;
 - d) production of feeds and feed additives for animals;
 - e) production of pharmaceuticals for veterinary use;
 - f) The breeding and growing on the territory of the Russian Federation of modified plants and animals as well as of microorganisms for agricultural use;
12. For the state registration of the modified organism an individual or a legal entity, regardless of its organizational and legal status, who carry out gene engineering activity on the territory of the Russian Federation (hereinafter in this Section - the Applicant) shall submit to the registration authority in paper hard copy or in electronic form signed with reinforced qualified electronic signature, including with the use of Federal public information system "Single Portal of State and Municipal Services (Functions)", the following:
- a) the application for the state registration of the modified organism in Russian language which contains the following information:
 - Full name and address of the Applicant and the manufacturer of the modified organism;
 - Taxpayer identification number (TIN) of the Applicant;
 - The full name of the modified organism, indicating its taxonomic status;
 - Information about the transformational event (characteristics of the genetic modification) as a code generated according to the All-Russian Classifier of transformational events approved by the Ministry of Education and Science of the Russian Federation;
 - Registration number of the certificate of the state registration of the modified organism (s) used for

development of the modified organism submitted for registration (in the case if modified organism was developed on the basis of another modified organism);

- Information on the registration of the modified organism abroad (if available);

- Kind of proposed intended use;

b) The conclusion on the results of:

- Molecular genetic study (regardless of the intended use of the modified organism);

- Medical and biological assessment of safety (for the intended uses provided for in subparagraphs "a" and "b" of paragraph 11 of the present Rules);

- Sanitary-epidemiological expertise (for the intended uses provided for in subparagraphs "c" of paragraph 11 of the present Rules);

- Biological safety (for the intended uses provided for in subparagraphs "d" - "f" of paragraph 11 of the present Rules);

c) Information on the available positive conclusion of the State Ecological Expertise (for the intended use, provided in subparagraph "f" of paragraph 11 of the present Rules). For the state registration the registration authority requests the necessary information on the execution and the results of the state ecological expertise, which is in the possession of the Federal Service for Surveillance in the Sphere of Environmental Management, in accordance with the order established by the Federal Law "On Organization of Provision of Federal and Municipal Services." The conclusion may be submitted by the Applicant on his own initiative;

13. It is not permitted to indicate several modified organisms in one application for registration.

The conclusions, provided in subparagraph "b" of paragraph 12 of the present Rules, are issued by organizations (testing laboratories) engaged in carrying out expertise (studies) in accordance with methods of conduct of expertise for each kind of intended use of modified organisms approved by the Ministry of Health of the Russian Federation, the Ministry of Agriculture of the Russian Federation and the Federal Service for Surveillance of Consumer Rights Protection and Human Welfare. In the course of conduct of such expertise (studies) special conditions for the use of the modified organism, including for the production of a specific kind of product, may be envisaged (hereinafter - the special conditions of use).

The State Ecological Expertise is conducted by the Federal Service for Surveillance in the Sphere of Environmental Management in accordance with the Federal Law "On Ecological Expertise".

14. The modified organism that was registered for the certain type of intended use may also be registered for another type of intended use. To do this, the Applicant should submit to the registration authority on paper or in the form of electronic document signed by reinforced qualified electronic signature, including with the use of the federal public information system "Single Portal of State and Municipal Services (Functions)" the following:

- a) The Application that is made in Russian language and contains the information required by subparagraph "a" of paragraph 12 of these Rules, as well as registration number of the previously issued certificate of state registration of the modified organism;

- b) conclusions provided by subparagraphs "b" and "c" of paragraph 12 of these Rules necessary to implement the state registration of the modified organism with due regard to the requested new kind of intended use;

15. Registration Authority:

- a) within a period not exceeding 30 days from the date of receipt of the documents mentioned in paragraphs 12 and 14 of these Rules:

- Verifies the information contained therein;
 - Makes a decision on the state registration of the modified organism and informs the Applicant of the decision;
 - Makes a decision on the refusal of state registration of the modified organism, and sends a reasoned refusal to register the modified organism to the Applicant;
- b) within 15 days from the date of the decision on the state registration of the modified organism:
- Includes the information on the modified organism to the consolidated register with assigning a registration number;
 - Issues for the Applicant the certificate of the state registration of the modified organism containing registration number, the kind (s) of the intended use of the modified organism, and special conditions of use (if any), on paper or in electronic form document at the choice of the Applicant;

16. In the case envisaged by paragraph 14 of the present Rules the registration authority issues the certificate of the state registration of modified organism indicating the new kind of intended use of the modified organism. For one modified organism certificates of the state registration of modified organism for various intended use of it can be issued;

17. The state registration of the modified organism may be refused in the case of non-compliance with the requirements specified in paragraphs 12 and 14 of these Rules, and in the case of the conclusion indicating negative impact of the modified organism on humans and the environment.

III. The state registration of products

18. Products are subject to state registration only after the state registration of modified organisms, with which use they are obtained and (or) which they contain, and can be used only for the purposes for which these modified organisms were registered;

19. For state registration of products a legal entity who carries out manufacturing (supply) of the products (hereinafter in this Section - the Applicant) shall submit to the registration authority, as paper hard copy or in electronic document signed with the reinforced qualified electronic signature including with the use of Federal public information system "Single Portal of State and Municipal Services (Functions)", the following:

a) The application for the state registration of the products in Russian language which contains the following information:

- Full name and address of the Applicant;
- The registration number of the certificate of state registration of the modified organism (organisms), with which use the products are obtained or which they contain;
- Composition of the products, including information on the quantity of the modified organism (organisms) in the products;
- Information on the registration of the products abroad (if available);

b) the conclusion on the results of molecular genetic study envisaged in the second indent of sub-paragraph "b" of paragraph 12 of these Rules (in regard to the confirmation of presence of the declared modified organism (s) in the registered products);

20. Registration Authority:

a) within a period not exceeding 30 days from the receipt of the documents mentioned in paragraph 19 of these Rules:

- Verifies the information contained therein;
- Makes a decision on the state registration of products and informs the Applicant of such a decision;
- Makes a decision on the refusal of state registration of products and sends to the Applicant a

reasonable refusal of the state registration of products;

b) Within 15 days from the date of the decision on the state registration of products:

- includes information on products in the Consolidated Register with assignment of the registration number;

- Issues for the Applicant the certificate containing registration number and the special conditions of use (if available) on paper or in electronic form as preferred by Applicant;

21. The state registration of products can be refused in the case of non-compliance with the requirements specified in paragraph 19 of these Rules.

IV. Maintaining Consolidated Register

22. Consolidated register is maintained by the Ministry of Health of the Russian Federation in electronic form in compliance with the requirements, established by legislation of the Russian Federation on information, information technologies and protection of information.

The relevant information is entered into the Consolidated Register by the registration authorities in compliance with the order, established by the Ministry of Health of the Russian Federation in concurrence with the Ministry of Mass Communications of the Russian Federation, the Ministry of Education and Science of the Russian Federation, the Ministry of Agriculture of the Russian Federation, and the Federal Service for Surveillance of Consumer Rights Protection and Human Well-Being;

23. Consolidated Register includes:

- Register of modified organisms;
- Register of products.

24. The register of modified organisms contains the following information:

- a) Registration number and the name of the modified organism, indicating its taxonomic status, and information on a transformational event (genetic characteristics of the modification) as a code formed according to the All-Russian Classifier of the transformational events;
- b) Full name and address of the applicant indicated in Section II of these Rules, and the manufacturer of the modified organism;
- c) Information on the kind (kinds) of the intended use of the modified organism and established special conditions of use (if any);
- d) Information on the conducted expertise (studies) and established special conditions of use (if any);
- e) Information on the organizations (testing laboratories) which conducted the expertise (studies);
- f) Information on cancellation of the certificate of the state registration of modified organism.

25. Register of products includes the following information:

- a) the registration number and the name of the product;
- b) the registration number of the modified organism (organisms), with use of which it was obtained and (or) which it contains;
- c) the full name and address of the Applicant, indicated in Section III of these Rules;
- d) information on established special conditions of use (if available);
- e) information on cancellation of the certificate of the state registration of product.

26. The information in the consolidated Register is open and publicly available for individual and legal entities and posted on the official site of the Ministry of Health of the Russian Federation in the information-telecommunication network "Internet".

27. Registration authorities post on their official sites in the information and telecommunication

network Internet, as well as in the federal state information system "Single Portal of State and Municipal Services (Functions) ":

- a) the information on the modified organisms registered by them, which is contained in the Register of the modified organisms (name of the modified organism and its transformational event, kinds of intended use of the modified organism, information on special conditions of use and on cancellation of the certificate);
- b) information on the products registered by them, which is contained in the Register of products (product name, modified organism (s), with which use the product was obtained, or which it contains, registration number of this modified organism (s), information on special conditions of use and on cancellation of the certificate of the state registration of product);
- c) lists of organizations (testing laboratories), which conduct appropriate expertise (studies), their location and phone numbers;
- d) methods of conduct of relevant expertise (studies);
- e) the procedure for monitoring of impact of the genetically-engineered-modified organisms and products obtained with use of such organisms or containing such organisms on humans and environment.